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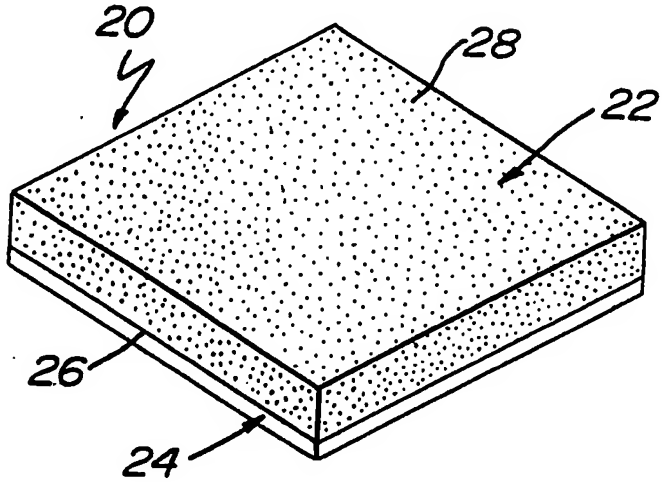

(57) Abstract

A method of preparing a pad to be applied to bleeding tissue comprising dissolving a resorbable reinforcing polymer in a solvent to form a solution. The solution is permitted to solidify into a desired configuration having an upper surface to form a reinforcing sheet (24). A sheet (22) of resorbable base layer material is then secured to the upper surface of the product and then allowed to dry. The base layer comprises e.g. collagen. The reinforcing means comprises material to render the pad resistant to tearing when wet.

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PADS, METHODS OF MAKING, AND METHODS OF USE FOR WOUND DRESSING, SURGICAL REINFORCEMENT AND HEMOSTASIS PROMOTION

Field of the Invention

This invention relates generally to medical devices and methods of use, and more particularly to pad-like members arranged to be used to effect the dressing of wounds, reinforcement of surgically sutured tissue, and therapeutic treatment of traumatized tissue or organs.

Background of the Invention

Various patents have disclosed dressings for applications to wounds. Examples of such patents are United States Patents Nos. 4,404,970 (Sawyer), 4,664,662 (Webster), 4,759,354 (Quarfoot), 4,789,401 (Ebinger et al.), 4,860,737 (Lang et al.), 4,909,244 (Quarfoot et al.), and 4,997,425 (Shioya et al.).

In United States Patent No. 4,759,354 (Quarfoot) there is disclosed a dressing for external wounds including a hemostatic, e.g., collagen, pad or layer, backed up by an adhesive layer, and an oxygen and vapor permeable outer layer or sheet. In United States Patent No. 4,997,425 (Shioya et al.) there is disclosed a dressing for treating wounds, such as those resulting from burn or trauma. That dressing is designed to absorb wound exudate to produce a firm primary vital adhesion to the surface of the wound and to encourage the development of fibroblast and capillaries to promote secondary vital adhesion. In particular, that dressing is in the form of a sponge layer composed of a polyamino acid. In one embodiment a non-resorbable reinforcing material, e.g., silicone gauze or nylon mesh, is embedded within the sponge layer for the stated purpose of endowing mechanical strength to the wound dressing and for facilitating the peeling off of the porous layer in some applications, e.g., after the dressing is used for treating second and third degree burns.

Various collagen pads are commercially available for use during surgery to control bleeding. One example of such pads is that sold under the Trademark HELISTAT by Collatec, Inc. Prior art collagen pads are typically formed

from collagen particles and fibers made into an aqueous slurry and then freeze dried into a relatively thin, e.g., one eighth to one quarter inch thick sheet. Typically such pads are used in sizes from three by four inches to ten by ten inches.

While each of the foregoing prior art dressings or pads may be generally suitable for its intended purpose(s), e.g., to absorb blood or exudate, effect hemostasis, promote healing, etc., each nevertheless suffers from one or more drawbacks. For example, the prior art collagen pads exhibit a very low tensile strength when wet, e.g., exposed to blood, so that they are susceptible to tearing or falling apart. The wound dressings disclosed in United States Patents Nos. 4,759,354 (Quarfoot) and 4,997,425 (Shioya et al), while perhaps more resistant to tearing, appear limited to external application. For example, the existence of a non-resorbable reinforcing layer in the Shioya et al patent would render it unsuitable for internal use inasmuch as would likely tend to result in the formation of unwanted scar tissue.

In the British Journal of Urology, Vol. 68, No.4, pp. 421-424 (October 1991), R. Scott et al. disclose a composite membrane comprised of a hemostatic collagen Vicryl mesh to be used in renal surgery. The composite membrane is a collagen film reinforced with Vicryl mesh which is claimed to result in a biodegradable composite material which is capable of being sutured. Other information about the dimensional and other characteristics of the membrane is unavailable. It is submitted that this membrane composition which utilizes cross-linked collagen to increase absorption time, would cause the collagen film to be somewhat brittle. Applicants believe that this brittleness would make the film essentially unusable in any application where the device must be bent or wrapped around a tissue. It should be noted that this article appears to describe that the membrane is a flat sheet which is simply placed onto the surface of the tissue and sutured into place.

Thus, a need currently exists for a pad and a method of making a pad formed of a hemostatic material, e.g., collagen, to promote hemostasis and tissue healing, yet which is resistant to tearing when wet, e.g., in the presence of blood, and which can be left within the body of the being to be absorbed thereby with minimal scar tissue formation.

Objects of the Invention

Accordingly, it is a general object of this invention to provide medical pads and methods of manufacture and use which overcome the disadvantages of the prior art and which fulfill the need set forth above.

It is another object of this invention to provide medical pads which are easy to use and effective for promoting hemostasis of bleeding tissue (internal or external).

It is another object of this invention to provide medical pads which are easy to use and effective for expediting suturing of tissue (internal or external).

It is still a further object of this invention to provide medical pads which are easy to use and effective for therapeutically treating traumatized tissue or organs within the body of a living being.

It is yet a further object of this invention to provide medical pads which can be readily manufactured, are simple in construction, and low in cost.

It is yet another object of this invention to provide medical pads which have a pore size which promotes cellular growth when applied to tissue or organs.

It is still yet another object of this invention to provide a medical pad which is capable of swelling when in place to permit the pad to fill an opening.

Summary of the Invention

These and other objects of this invention are achieved by providing medical pads and methods of making and using the same. The medical pads are arranged for application to bleeding tissue of a being. The pads comprise a base layer and reinforcing means connected thereto. The

base layer has a pair of outer surfaces and comprises a sheet of resorbable, hemostatic material, e.g., collagen. The reinforcing means comprises a sheet of a resorbable material which is resistant to tearing and which is fixedly secured to the base layer to render the pad resistant to tearing when wet.

The method of making the pad of this invention basically comprises providing a base layer of a resorbable hemostatic material, providing resorbable reinforcing means, and fixedly securing the reinforcing means to the base layer to render the pad resistant to tearing when wet.

One method of use of the pad of this invention is for effecting hemostasis of bleeding tissue, e.g., internally located tissue. That method entails applying the pad to the bleeding tissue so that one of the surfaces of the pad having at least a portion of the base layer exposed is in contact with the tissue.

Another method of use of the pad of this invention is for suturing of bleeding tissue, e.g., internally located tissue, of a living being. That method entails applying the pad to the bleeding tissue so that one of the surfaces of the pad having at least a portion of the base layer exposed to the bleeding tissue is in contact with the tissue, and then suturing that tissue through the pad.

Another method of use of the pad of this invention is for therapeutically treating traumatized tissue within the body of a living being. That method entails applying the pad about the tissue to form an enclosure, enclosing the tissue therein so that one of the surfaces of the enclosure having at least a portion of the base layer exposed is in contact with the tissue, and leaving that enclosure in place to promote hemostasis.

In accordance with all aspects of this invention, if desired, the pad may include one or more active agents, e.g., biologicals, chemicals, pharmaceuticals, antibiotics, vitamins and/or antiseptics, therein. In addition an absorbable radio-opaque material may be included in the pad.

One method of preparing a pad of this invention to be applied to bleeding tissue comprises the steps of suspending a resorbable polymer in a solvent to form a solution. The solution is permitted to solidify into a film or sheet in the desired configuration having an upper surface to form a reinforcing sheet. A sheet of resorbable base layer material is then secured to the upper surface of the product and then allowed to dry.

Brief Description of the Drawings

Other objects and many of the attendant advantages of this invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Fig. 1 is a perspective view of one embodiment of a pad constructed in accordance with this invention;

Fig. 2 is a perspective view of a second embodiment of a pad constructed in accordance with this invention;

Fig. 2A is a perspective view of a third embodiment of a pad constructed in accordance with the invention;

Fig. 3 is a perspective view of a fourth embodiment of a pad constructed in accordance with this invention;

Fig. 4 is a perspective view of a fifth embodiment of a pad constructed in accordance with the invention;

Fig. 5 is a sectional view showing one use of a pad constructed in accordance with this invention;

Fig. 6 is a sectional view showing another use of a pad constructed in accordance with this invention; and

Fig. 7 is a perspective view, partially in section, showing yet another use of a pad constructed in accordance with this invention.

Detailed Description of the Preferred Embodiments

Referring now in greater detail to the figures there is shown at 20 in Fig. 1 one embodiment of a pad constructed in accordance with this invention. The pad 20 basically comprises a base layer 22 and a reinforcing sheet 24. The base layer is a relatively thin, sheet-like member

having a pair of outer surfaces 26 and 28. The reinforcing sheet comprises a very thin film which is secured to the surface 26 of the base layer 22 as will be described later.

The base layer and reinforcing sheet are each of the same size and shape, albeit of different thickness. In the embodiment shown the pad is square in shape and is approximately 10 inches (25.4 cm) by 10 (25.4 cm) inches. It can be of any thickness from one sixteenth inch (1.59 mm) to one half inch (12.7 mm) thick. Other shapes and dimensions for the pad are contemplated within the scope of this invention. In fact, the pad 20 can be readily cut to any size and shape as desired. Thus, a surgeon can tailor the pad 20 (or any pad constructed in accordance with this invention) to the size and shape desired for the procedure being accomplished.

The base layer 22 is formed of any resorbable, hemostatic material, e.g., the aforementioned HELISTAT (trademark) collagen. Such a material exhibits a relatively low tensile strength when subjected to blood. Thus, the reinforcing sheet 24 is selected to exhibit substantially greater wet strength than the base layer, e.g., is somewhat stretchable, yet tough, so that when it is secured to the base layer the resulting pad will be resistant to tearing or other damage when wet or in the presence of blood. In accordance with a preferred embodiment of this invention the sheet 24 is formed of a fifty-fifty polylactide and polyglycolide copolymer film, such as sold under the trademark MEDISORB by Medisorb International, Inc. and/or E.I. DuPont de Nemours, Inc., which is from 0.0005 inch (0.13 mm) to 0.01 inch (0.25 mm) thick to exhibit the desired properties.

Sheets formed using such a material are smooth and somewhat slippery. Thus, the presence of the sheet 24 on the surface 26 of the pad renders that surface more resistant to snagging than the uncovered collagen surface 28. This feature is desirable for some applications as will be described later.

It must be pointed out at this juncture that the sheet 24 of Fig. 1 need not be a continuous film. In this regard, in Fig. 2 there is shown an alternative embodiment of the pad of this invention. That pad is designated by the reference numeral 100 and is of somewhat similar construction to the pad 20 except that both of the base layer's outer surfaces 26 and 28 have a reinforcing sheet 24 secured thereto. In this embodiment at least one of the sheets 24, namely, the sheet on surface 28, is perforated with plural perforations or openings 40. Those perforations can be of any size and shape, as desired.

In Fig. 3 there is shown yet another alternative embodiment of the pad of this invention. That pad is designated by the reference numeral 200 and is of somewhat similar construction to the pad 20 except that both of the surfaces 26 and 28 have a reinforcing sheet 24 secured thereto and a third reinforcing sheet 24 is located within the base layer 22. To that end the base layer comprises a pair of layers 22A and 22B. Each of the layers 22A and 22B may be formed of a material similar to that of 22 of Fig. 1 or may be formed of other resorbable hemostatic materials. The resorbable hemostatic material making up the layer 22A may be chosen to exhibit characteristics the same as or different from the layer 22B. A reinforcing sheet 24 is interposed between the two layers 22A and 22B and is secured to each, whereupon the two layers are secured to each other. When so secured the outer surface of layer 22A forms the outer surface 26, while the outer surface of the layer 22B forms the outer surface 28. In this embodiment at least one of the sheets 24, namely, the sheet on the outer surfaces 26, is perforated by holes 40. The intermediate sheet 24, i.e., the sheet located between the layers 22A and 22B, may also be perforated, if desired.

It should be pointed out at this juncture that the reinforcing sheets 24 of any of the embodiments described heretofore need not be a film (perforated or unperforated). In this regard there is shown in Fig. 4 yet another

embodiment of the pad of this invention. That pad is designated by the reference numeral 300 and includes the heretofore identified base layer 22 and a reinforcing sheet 50. The sheet 50 is a web or mesh of fibers 52 formed of the same material as the sheet 24. Thus, any reinforcing sheet of any of the pads of this invention may be formed as a mesh or web of fibers 52 of a resorbable material, as shown in Fig. 4, in lieu of the perforated or unperforated sheets 24 described heretofore.

In Fig. 2A there is shown at 400 yet another alternative embodiment of the pad of this invention. That embodiment is similar to the embodiment 100 except for the fact that the reinforcing sheet 24 secured to the outer surface 28 of the base layer 22 has a rough textured outer surface, e.g., includes a large plurality of pointed projections 56. These projections serve to prevent the pad 400 from slipping once it is in place on the tissue by virtue of the engagement of those projections with the tissue. Thus, as will be appreciated by those skilled in the art the pad 400 is adapted for use on slippery tissue, e.g., the liver, intestines, etc., without requiring the pad to be sutured in place.

The textured surface of the sheet 24 of pad 400 can take various forms as desired, e.g., it may include long spikes or barbs, short spikes or barbs, combinations of long and short spikes or barbs, etc. Moreover, the projections can be in the form of hook-like members and/or loop-like member, like that of the components of a VELCRO (trademark) fastening system, to enable pads to be joined together. The textured sheets 24 can be prepared by any suitable technique. For example, the barbs or projections can be hot formed by a compression die having surface indentations corresponding to the barbs or projections. Alternatively the sheet 24 may be heated to a soft point and small pellets sprinkled on the surface and then pressed into place to secure them to the surface of the sheet.

No matter what the construction of the reinforcing sheet 24 is, it is preferably fixedly secured onto the contiguous surface of the base layer 22. The manner of securement can be effected by any suitable conventional application technique, e.g., evaporation deposition, flotation, lamination by hot compression molding or injection molding, etc.

One aspect of the various methods of use of the pads of this invention is to effect hemostasis of bleeding tissue. Thus, any of the pads 20, 100, 200, 300 or 400 is arranged to be applied directly onto such tissue. That tissue may be externally located or internally located. In any case, the pad is arranged to be applied so that at least some portion of its base layer engages the tissue. In the embodiment shown in Fig. 1, the pad 20 is applied so that the entirely exposed outer surface 28 of the base layer 22 engages the bleeding tissue. In the embodiments shown in Fig. 2 and 2A the pads 100 and 400, respectively, are each applied so that their outer surface 28 bearing the reinforcing sheet 24 having the perforations 40 therein engages the bleeding tissue. Accordingly, the portions of the base layer 22 exposed by the perforations 40 engage the bleeding tissue. In a similar manner, in the embodiment shown in Fig. 3, the pad 200 is applied so that the outer surface 28 bearing the reinforcing sheet 24 having the perforations 40 therein, engages the bleeding tissue. The pad 300 may be applied so that either of the surfaces 26 or 28 is in contact with the tissue since in either case the tissue will be able to engage the base layer either directly or through the interstices 54 of the mesh 50. It is preferable, however, that the surface 28 of the pad 300 engage the tissue, so that the mesh on the other surface will provide a relatively smooth protective outer surface for the pad, for reasons to be described hereinafter.

In all of the applications just described, blood from the bleeding tissue will be able to engage the collagen base layer 22, either by direct contact therewith or through

the perforations 40 or interstices 54, whereupon the collagen material can quickly effect hemostasis. Moreover, in all of those applications the surface of the pad opposite to the tissue engaging surface will have a reinforcing sheet 24 or 50 thereon. This sheet, being tough, protects the pad from damage during the surgery or other procedure being conducted on the patient, and by virtue of its smoothness reduces the possibility of a snagging hazard.

In addition, to promote cell growth when the pad is applied to tissue or organs, the pad should be comprised of a material having a pore size of approximately 100μ.

Since the entire pad of embodiments 20, 100, 200, 300 and 400 is resorbable, it may be left in place to be absorbed by the patient's body. This feature renders the pads of this invention particularly suitable for various surgical applications. Some examples of such applications are expediting the suturing of weak tissue together (as shown in Fig. 5, to be described later), effecting hemostasis of abdominal tissue after removal of highly vascular growths (as shown in Fig. 6, to be described later), and promoting healing and hemostasis of traumatized tissues or organs (as shown in Fig. 7, to be described later). In addition, since the pad is comprised of a swellable material, the pad is especially suitable for use in filling up holes with a conforming material, e.g., as a dental plug.

In applications wherein the pads are to be applied to externally located bleeding tissue the pad may be provided with a non-stick removable dressing. Such a pad is applied in the same manner as described heretofore, but is then taped down. The resorbable pad can be left in place to promote rapid tissue ingrowth.

Turning now to Fig. 5, and its alternative embodiments 100, 200, 300 and 400, the use of a pad 20 to facilitate the suturing of weak, bleeding tissue will now be described. Thus, as can be seen therein two pads 20 are applied to opposite sides of a joint 60 formed of a pair of tissue edges 62 and 64 to be sutured together. The pads 20

or the alternate embodiments are applied in the same manner as described earlier, i.e., so that the bleeding tissue engages the hemostatic base layer either directly or via perforations, or interstices in a reinforcing sheet. Once the pads 20 are in place one or more conventional resorbable sutures 66 can then be extended through the opposed pads and the interposed tissue, and the sutures knotted at 68. Thus, the pads 20 serve as bolsters to reinforce the sutured joint 60 and to expedite hemostasis.

Turning now to Fig. 6, and its alternative embodiments 100, 200, 300 and 400, the use of a pad 20 to facilitate hemostasis at a surgical site will now be described. As can be seen therein the surgical site comprises an abdominal wall 70 having muscle layers 72 thereover, and from which layers a highly vascular growth (not shown) had been removed leaving an area 74 of bleeding tissue. A pad 20 or an alternate embodiment is disposed over the area 74 so that the surface 28 of the pad's base layer 22 engages that tissue. The pad is secured in place via plural conventional resorbable sutures 76.

Turning now to Fig. 7, the use of a pad 20, and its alternative embodiments 100, 200, 300 and 400, to promote hemostasis of a traumatized tissue or organ will now be described. Thus, as can be seen, a hollow enclosure 80 is formed from plural pads 20 or alternate embodiments so that it encloses all or a portion of a traumatized organ. In the embodiment shown in this figure the organ comprises the lobe 82 of a liver having multiple surface lacerations 84. The enclosure 80 can be of any suitable shape, e.g., bag-like, and can be formed in situ by suturing one or more pads together about the entire organ or a portion of it, as desired. In particular, as shown in Fig. 7, two pads 20 are cut to the desired shape then sewn together in situ by plural peripheral resorbable sutures 86. In order to hold the enclosure 80 in place, it is sutured, via resorbable sutures 88, to the enclosed organ. In cases where the enclosure and

organ are shaped so that the enclosure cannot slip off the organ, the use of sutures 88 may be omitted.

In lieu of constructing the enclosure 80 in situ, for some applications it may be preformed and then introduced into the body of the being to receive the organ or organ portion therein. In any case the enclosure is applied in the same manner as described earlier, e.g., so that the bleeding tissue is engaged by the hemostatic base layer either directly or via perforations or interstices in a reinforcing sheet.

Any of the pads 20, 100, 200, 300 and 400 may include one or more active agents if desired. Examples of such agents are biologicals, chemicals, pharmaceuticals, antibiotics, antiseptics, vitamins, etc. Such agents may be incorporated in or on the base layer 22 and/or may be incorporated in or on the reinforcing layer. Moreover, the pads may include a resorbable radio-opaque material, such as that sold under the trademark Renografin-76 by Squibb Diagnostics, of New Brunswick, NJ, to provide a means for radiographic imaging of the tissue to which the pad is applied during the surgery or after the surgery has been completed.

As discussed earlier, in the embodiments of the pads 20, 100, 200, 300 and 400, the base layer is formed of a collagen, such as the HELISTAT collagen, and the reinforcing sheet (be it a film, web or mesh) is formed of a fifty-fifty polylactide and polyglycolide copolymer. However, it must be pointed out at this juncture that such materials are merely exemplary. Thus, various other resorbable materials, alone or in combinations, can be used. Some examples of reinforcing materials are poly(lactic/glycolic acids), poly(hydroxybutyrate), poly(caprolactones), poly(amino acids), poly(oxyethylene glycolate), poly(alkylene oxalates), poly(ethylene oxide/PET), poly(anhydrides) and poly(orthoesters).

So too, the base layer of the pad, need not be the specific HELISTAT collagen disclosed heretofore. In fact,

the base layer need not be a collagen at all, so long as it is formed of a material which is resorbable and hemostatic. Other types of suitable resorbable base materials include, but are not limited to, oxidized regenerated cellulose, gelatin, polylactic acid, polyglycolic acid, poly(hydroxybutyrate), poly(caprolactones), poly(amino acids), poly(oxyethylene glycolate), poly(alkylene oxalates), poly(ethylene oxide/PET), poly(anhydrides) and poly(orthoesters) and blends thereof.

In order to prepare the pads of the present invention, it is preferable that the method steps of the present invention be performed in a sterile hood and that operators performing these steps wear masks, gloves and head covers to maintain sterility.

In order to prepare a device as shown in Fig. 1, the base layer and reinforcing material layer must be formed and joined. In one embodiment of the method of the present invention, the reinforcing material layer is first formed by providing a 15% weight/weight solution of a polylactide/glycolide polymer (in a ratio of 50:50) in ethyl acetate or acetone by first charging 170 gms of solvent to a beaker equipped with a magnetic stirrer. The solvent is stirred or mixed and brought to a temperature of about 30°C. Although any type of suitable polymers may be used with the present invention, the polylactide/glycolide polymers of this example were obtained from Medisorb Technologies International, Inc., located in Wilmington, DE, and sold under the trademark MEDISORB. The polymer pellets (e.g., 30 grams) are then added to the solvent slowly over about 10 minutes, with constant agitation to ensure complete wetting occurs. Once all of the polymer material has been added, the mixture is stirred until complete dissolution occurs.

Once the polymer is dissolved, the beaker is then covered and the solution allowed to cool to room temperature (approximately 25°C).

In order to obtain the pad in the desired configuration, trays are used to permit the solution to

solidify (e.g., form a sheet or film) as desired. Although any suitable type of container may be used, it is preferable to use trays having a TEFLON or other suitable non-stick surface to hold the solution. The surface of a TEFLON tray (e.g., 9.5" x 13.25") is first cleaned with a solvent such as ethyl acetate or acetone (the same solvent used to dissolved the polymer) and the trays are permitted to dry.

The previously prepared polymer solution is then poured into the tray. In order to assure uniform film thickness, if that feature is desired in the final configuration, the tray should be level. The polymer solution in the tray is then allowed to dry for a minimum of 12 hours at room temperature. If a rectangular sized tray is used, the polymer solution, when dried, will form a rectangular sized sheet.

A second aliquot of the polymer/solvent solution, as previously described above is used to bind the resorbable reinforcing material to the base layer.

A sheet of a resorbable base layer material is cut and/or formed to the desired dimensions. Any suitable type of base layer material can be used, such as collagen, oxidized regenerated cellulose, polylactide/glycolide and/or gelatin. In addition, many forms of these materials may be used, e.g., foams, films, powders, etc. Foam forms of these materials are especially useful in the present invention as they have pores which promote cellular growth and assist in promoting hemostasis.

One suitable type of resorbable base layer material is a collagen pad is that sold by Colla-Tec, of Plainsborough, NJ, under the trademark HELISTAT. Those collagen pads are comprised of cross-linked bovine collagen, and have dimensions of approximately 3 x 4 inches. Other types of materials which may be used in place of collagen, include, but are not limited to other resorbable materials, such as the well-known hemostat sold by Johnson & Johnson Products, New Brunswick, NJ, under the trademark SURGICEL comprised of an oxidized regenerated cellulose material in a

porous pliable mesh, and the gelatin material sold under the trademark GELFOAM by the Upjohn Company, Kalamazoo, MI, which is a porous, pliable matrix prepared from purified gelatin. Other suitable base layer materials may also include a sheet of a resorbable fiber made of polylactic or polyglycolic acid, e.g., in a woven gauze.

The second aliquot of the polymer/solvent solution is applied to the upper surface of the dried polymer sheet in the trays with a suitable applicator. A paint brush having nylon bristles works suitably well, as does a roller having a wooden rolling surface and sold by Fischer Scientific of Malvern, PA. An even coating of the solution is applied to the upper surface of the dried polymer film and then the previously sized resorbable base layer (e.g., collagen pad) is applied on top thereof. Pressure is applied to the upper surface of the resorbable base layer using a steel type press, sold by Haechtel Instrument Co. which is described as double-sided steel press. Alternatively, a roller such as a rolling pin, may be used to insure intimate contact between the resorbable reinforcing layer and the base layer.

The reinforcing means/base layer combination is allowed to dry for at least four hours at room temperature (approximately 25°C) and is then placed in a vacuum oven at approximately 30°C at full vacuum overnight to aid in securing the structure and to remove the solvent. One type of such a vacuum is model no. DP-41, sold by American Scientific Products, of Edison, NJ.

Afterwards, the final product may be cut into the desired sizes and placed in appropriate packaging for sterilization.

In order to prepare the other various embodiments shown in Figs. 2-4, similar steps are performed and each of the various layers is sequentially layered as desired, prior to the overnight drying phase as set forth above. Each successive layer may be bonded to the next successive layer by utilizing another aliquot of the polymer/solvent solution to bind the alternating layers together. These various steps

may be repeated as necessary in order to obtain the desired number of alternating layers of the base layer and the reinforcing means.

In another alternative method of the present invention, the polymer film may first be coated onto a release liner and dried in an oven as set forth above. The film may then be coated with the polymer/solvent solution as set forth above and the resorbable base layer placed on top of the reinforcing layer. The combination may then be dried and sized as previously set forth. Alternatively, the film cast from release liner can be laminated with heat of approximately (75°-80° c.) for about thirty seconds and with sufficient pressure to ensure intimate contact by a heated press as set forth herein to form the various embodiments.

The weight/weight percentage of polymer/solvent in the present invention is approximately 15%. Accordingly, other weight/weight ranges which will produce a suitable product for use in the present invention includes the approximate range of 10-40% weight/weight polymer/solution.

It should be noted that the above steps of the method of the present invention are merely exemplary and that the invention should not be limited to merely the above steps.

Without further elaboration the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adapt the same for use under various conditions of service.

CLAIMS

What we claim is:

1. A method of preparing a pad to be applied to bleeding tissue comprising the steps of:

(a) suspending a resorbable reinforcing material in a solvent to form a solution;

(b) permitting the solution to solidify into a desired configuration having an upper surface to form a reinforcing means;

(c) securing a sheet of resorbable base material to the upper surface of the product of step (b); and

(d) drying the product of step (c).

2. The method of claim 1 additionally comprising the step of selecting the resorbable reinforcing material from the group consisting of polylactide, glycolide and blends thereof.

3. The method of claim 1 additionally comprising stirring the solvent as the resorbable reinforcing material is suspended therein.

4. The method of claim 3 additionally comprising suspending the resorbable reinforcing material in a solvent and selecting the solvent to have a temperature of approximately 30°C.

5. The method of claim 1 additionally comprising the step of selecting the desired configuration to be a sheet.

6. The method of claim 1 additionally comprising the step of spreading a portion of the solution in between the upper surface of the product of step (b) and the resorbable base material to aid in securing the product of step (b) and the resorbable base material together.

7. The method of claim 6 additionally comprising the step of applying pressure to the resorbable base material.

8. The method of claim 7 additionally comprising selecting the pressure to be applied by using a rolling means on an upper surface of the resorbable base material or by pressing the upper surface of the resorbable base material.

9. The method of claim 1 additionally comprising the step of drying the product of step (c) under vacuum at a temperature of approximately 30°C for approximately 12 hours.

10. The method of claim 1 additionally comprising selecting the resorbable base material from the group consisting of collagen, oxidized regenerated cellulose, gelatin, polylactic acid, polyglycolic acid, poly(-hydroxybutyrate), poly(caprolactones), poly(amino acids), poly(oxyethylene glycolate), poly(alkylene oxalates), poly(ethylene oxide/PET), poly(anhydrides) and poly(orthoesters) and blends thereof.

11. The method of claim 1 additionally comprising the step of suspending the resorbable reinforcing material in the solvent in a ratio of approximately 15% weight/weight.

12. The method of claim 2 additionally comprising selecting the resorbable reinforcing material to be a mixture of polyglactide and glycolide in a ratio of approximately 50:50.

13. A method of preparing a pad to be applied to bleeding tissue comprising the steps of:

(a) preparing a solution comprising approximately 15% weight/weight of a resorbable reinforcing material and a solvent by heating the solvent to an approximate temperature of 30°C and then adding the polymer to the solvent while stirring;

(b) permitting the solution to cool to approximately room temperature;

(c) pouring the solution into a container to permit the solution to solidify into a sheet having an upper surface;

(d) applying an aliquot of the solution to the upper surface of the product of step (c);

(e) layering a sheet of a resorbable base layer material on the upper surface of the product of step (d);

(f) applying pressure to the product of step (e); and

(g) drying the product of step (f) under vacuum at a temperature of approximately 30°C for approximately 12 hours.

14. The method of claim 13 additionally comprising the step of selecting the reinforcing material from the group consisting of polylactide, polyglycolide and blends thereof.

15. The method of claim 13 additionally comprising the step of selecting the solvent from the group consisting of ethyl acetate and acetone.

16. The method of claim 13 additionally comprising the step of selecting the resorbable base material from the group consisting of collagen, oxidized regenerated cellulose, gelatin, polylactic acid, polyglycolic acid, poly(-hydroxybutyrate), poly(caprolactones), poly(amino acids), poly(oxyethylene glycolate), poly(alkylene oxalates), poly(ethylene oxide/PET), poly(anhydrides) and poly(orthoesters) and blends thereof.

17. A method of making a medical pad for application to bleeding tissue, the method comprising:

(a) providing a base layer of a resorbable material, and reinforcing means for the pad, the reinforcing means comprising a sheet of a tear resistant resorbable material; and

(b) fixedly securing the reinforcing means to the base layer to render the pad resistant to tearing when wet.

18. The method of Claim 17 additionally comprising the step of selecting the reinforcing means to be secured to the base layer by a process selected from the group consisting of evaporation, flotation, hot compression molding and injection molding.

19. The method of Claim 18 additionally comprising the step of selecting the resorbable material to comprise collagen and selecting the reinforcing means to comprise a polylactide and polyglycolide copolymer.

20. The method of Claim 18 additionally comprising the step of forming the pad into a hollow enclosure to receive the tissue therein.

21. The method of Claim 18 additionally comprising the step of selecting the pad to additionally comprise a radio-opaque material.

22. The method of Claim 18 wherein the pad additionally comprises an upper and lower surface and the method additionally comprises the step of securing the reinforcing means to both the upper and lower surfaces.

23. The method of Claim 18 additionally comprising the step of selecting the reinforcing means to have perforations therethrough.

24. The method of Claim 18 additionally comprising the step of selecting the reinforcing means to have a textured surface.

25. The method of Claim 19 additionally comprising the step of selecting the pad to additionally comprise at least one therapeutic agent.

26. A resorbable pad for application to bleeding tissue comprising at least one base layer and reinforcing means connected thereto, the base layer being formed of a resorbable material, the reinforcing means comprising at least one sheet of a resorbable material which is resistant to tearing, the reinforcing means being fixedly secured to the base layer to render the pad resistant to tearing when wet.

27. The pad of Claim 26 wherein the base layer comprises a pair of outer surfaces and the reinforcing means is secured to at least one of the outer surfaces.

28. The pad of Claim 27 wherein the reinforcing means is secured to both of the outer surfaces.

29. The pad of Claim 26 wherein the reinforcing means is located within the interior of the base layer.

30. The pad of Claim 26 wherein the reinforcing means is located within the interior of the base layer and is also secured to both of the outer surfaces.

31. The pad of Claim 26 wherein the reinforcing means is perforated.

32. The pad of Claim 26 wherein the reinforcing means comprises a mesh.

33. The pad of Claim 26 wherein the reinforcing means comprises a film.

34. The pad of Claim 26 wherein the base layer comprises a resorbable material selected from the group consisting of collagen, oxidized regenerated cellulose, gelatin, polylactic acid, polyglycolic acid, poly(-hydroxybutyrate), poly(caprolactones), poly(amino acids), poly(oxyethylene glycolate), poly(alkylene oxalates), poly(ethylene oxide/PET), poly(anhydrides) and poly(orthoesters) and blends thereof.

35. The pad of Claim 27 wherein the reinforcing means secured to at least one of the outer surfaces is perforated.

36. The pad of Claim 35 wherein the perforated reinforcing means comprises a textured surface.

37. The pad of Claim 36 wherein the textured surface includes plural projections.

38. The pad of Claim 37 wherein the projections are pointed.

39. The pad of Claim 31 wherein the reinforcing means is perforated.

40. The pad of Claim 30 wherein at least one of the reinforcing means located within the interior of the base or the reinforcing means secured to either of the outer surfaces is perforated.

41. The pad of Claim 8 wherein the film is a copolymer film.

42. The pad of Claim 26 wherein the reinforcing means comprises a copolymer film.

43. The pad of Claim 26 wherein the base layer comprises a pair of layers secured to each other with the reinforcing means interposed therebetween, each of the layers of the pair being formed of a resorbable material.

44. The pad of Claim 26 wherein of the pad additionally comprises a radio-opaque material.

45. The pad of Claim 26 wherein the pad is formed into a hollow enclosure for receiving the tissue therein.

46. The pad of Claim 26 wherein the reinforcing means is applied on the base layer by a process selected from the group consisting of evaporation, flotation, hot compression molding and injection molding.

47. The pad of Claim 26 additionally comprising at least one therapeutic agent.

48. The pad of Claim 26 wherein the reinforcing means comprises a polylactide and polyglycolide copolymer.

49. The pad of Claim 47 wherein the base layer comprises collagen and wherein the therapeutic agent is located within the base layer.

50. The pad of Claim 26 wherein the base layer is hemostatic.

51. The pad of Claim 26 wherein the reinforcing means is hemostatic.

52. The pad of Claim 50 wherein the reinforcing means is hemostatic.

FIG.1

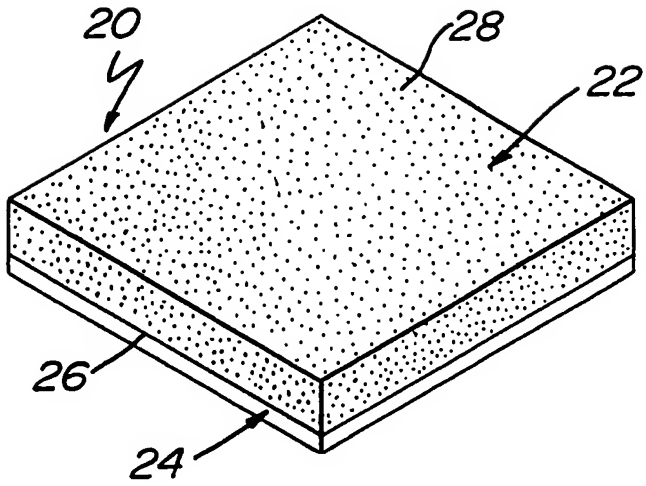


FIG.2

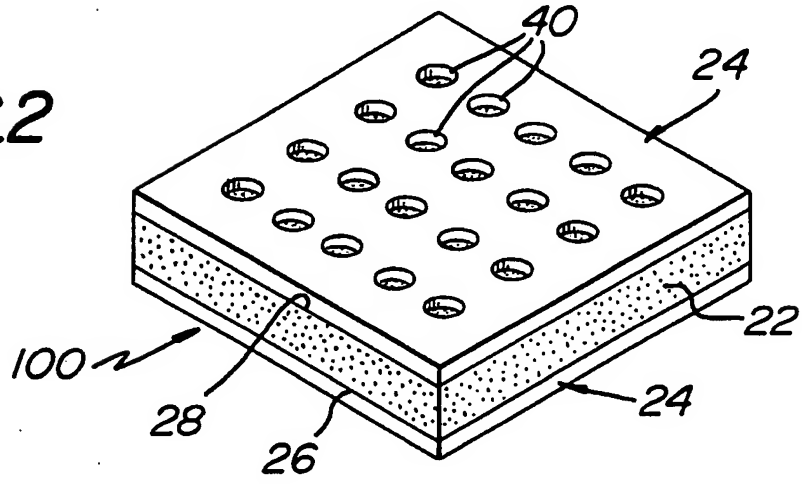


FIG.2A

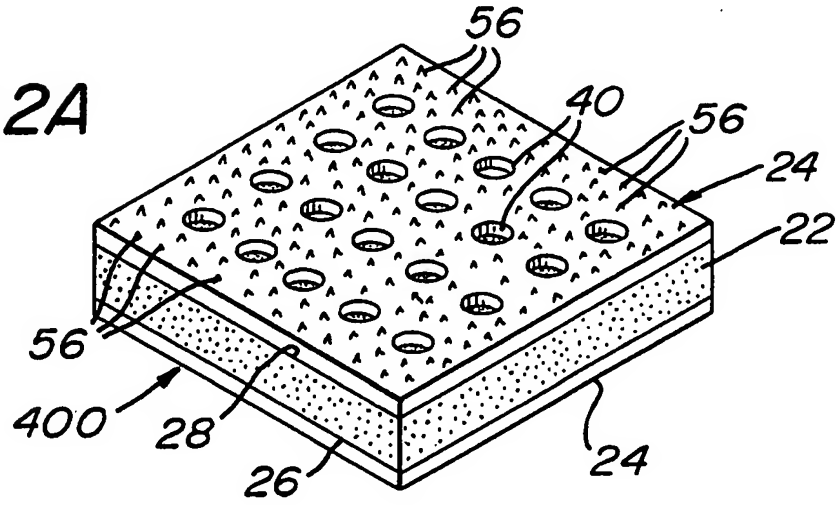


FIG.3

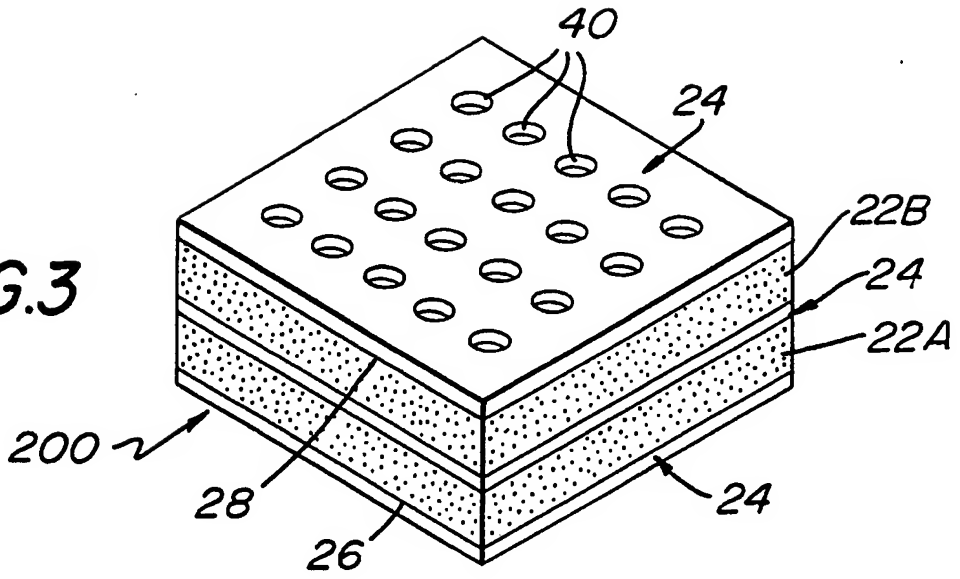


FIG.4

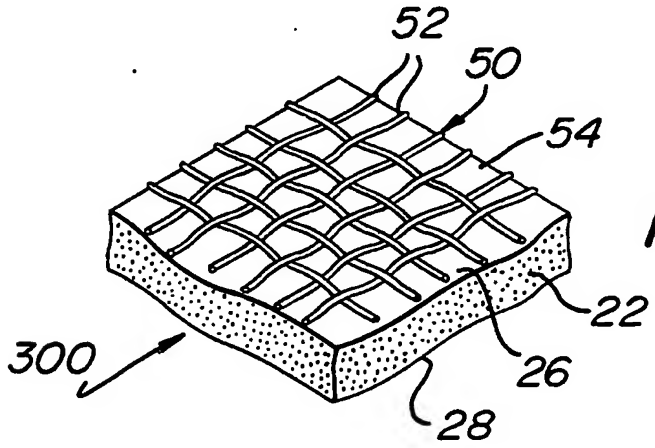


FIG.5

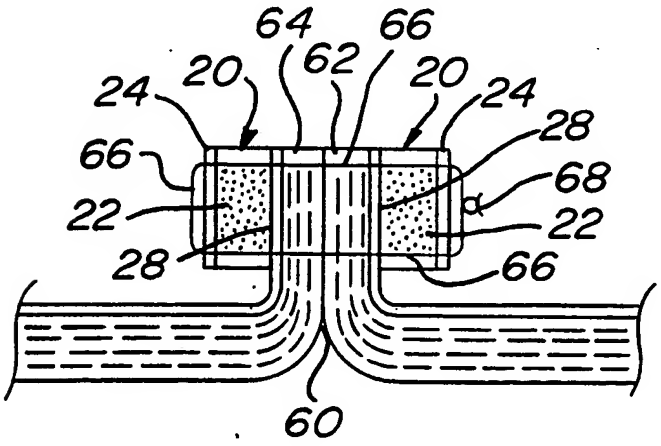
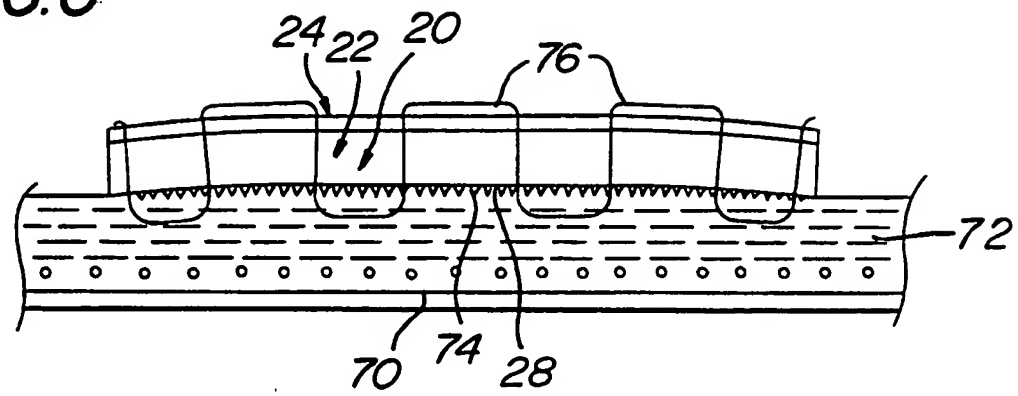


FIG.6



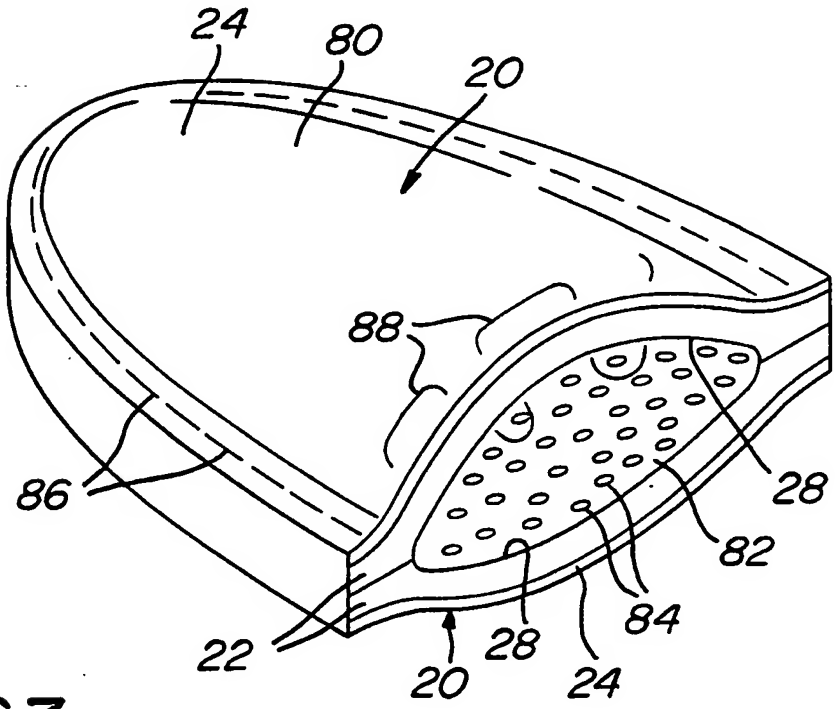


FIG.7

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 92/10546

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F13/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	BRITISH JOURNAL OF UROLOGY vol. 68, no. 4, October 1991, pages 421 - 424 R.SCOTT ET AL. 'First Clinical Report of a New Biodegradable Membrane for Use in Urological Surgery' cited in the application	17, 26-27, 32,34, 48,50
A	see page 421, left-hand column, line 1 - line 10 see page 421, right-hand column, line 4 - line 5 see page 422, right-hand column, line 51 - page 423, left-hand column, line 14	2,5,10, 14,16,19

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° Special categories of cited documents : [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
31 MARCH 1993	23. 04. 93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	NICE P.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X	FR,A,2 377 205 (BATTELLE MEMORIAL INSTITUTE) 11 August 1978	1-5,17, 26-27, 33,41-42
A	see page 4, line 4 - line 7 see page 4, line 34 - page 5, line 2 see page 6, line 24 - line 29 see page 8, line 12 - line 18 see page 9, line 10 - line 13 see page 10, line 25 - line 31 see page 12, line 12 - line 19	6,9,11, 13
X	EP,A,0 194 192 (ETHNOR) 10 September 1986	17,26, 29,32, 34,43, 48,50
A	see claims 1-5; figures	10,12, 14,16,19
X	DE,A,3 619 197 (ETHICON) 10 December 1987	17, 26-28, 31-35, 39, 41-42,48
A	see abstract see claims 3-4; figure 2	10,14, 16,23
X	EP,A,0 099 758 (UNIVERSITY OF STRATHCLYDE) 1 February 1984	17, 26-27, 33-34, 47,49
A	see page 1, line 26 - line 31 see page 2, line 10 - line 20 see page 5, line 23 - line 33 see page 6, line 4 - line 8 see page 6, line 14 - line 15	10,14,16
X	GB,A,1 186 796 (PARACHEM) 2 April 1970	26-27, 33-34,47
A	see page 1, line 53 - line 70 see page 2, line 24 - line 34 see page 2, line 65 - line 70	7-8,13
A	DE,A,2 804 683 (AMERICAN CYANAMID) 17 August 1978 see claims 1-3	24-25, 36-38, 51-52

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	EP,A,0 265 157 (ETHICON) 27 April 1988 see abstract see column 4, line 33 - line 4; figure 8	20,45
A	DE,A,2 535 760 (TUWA-PLASTIK) 10 June 1976 see page 7, line 13 - line 14 see claim 15	18,46

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9210546 SA 68052

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 31/03/93
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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		AU-A-	3244778	26-07-79
		BE-A-	862981	17-07-78
		CA-A-	1092026	23-12-80
		DE-A,C	2802295	20-07-78
		GB-A-	1562373	12-03-80
		JP-A-	53090691	09-08-78
		LU-A-	78882	18-09-78
		NL-A-	7800531	20-07-78
		SE-B-	439244	10-06-85
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		DE-A-	3781958	05-11-92
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		JP-A-	63046151	27-02-88
		US-A-	4796603	10-01-89
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		EP-A-	0227955	08-07-87
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		BE-A-	715578	25-11-68
		CH-A-	492457	30-06-70
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		FR-A-	2380365	08-09-78
		JP-A-	53100693	02-09-78

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The members are as contained in the European Patent Office EDP file on 31/03/93
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		SE-A- 7801662	13-10-78
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		CA-A- 1297641	24-03-92
		DE-A- 3783317	11-02-93
		JP-A- 63102754	07-05-88
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